Symptom Benefit Working group

General Assembly

Chicago, Friday, May 31, 2013

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

Chairs: F Joly, J McAlpine

Agenda

- **Lecture**

- Update PRO-clinical trials — *M Friedlander*

- **Ovarian Cancer**

- Symptom Benefit study — *M Friedlander*
- Elderly
  - EWOC study — *G Freyer*
  - GOG 273 — *F Joly for G Fleming*
- Patient satisfaction (expression III/IV) — *J Sehouli*
- Others

- **Endometrial Cancer:** — *F Joly & J McAlpine*

- Update of the brainstorming session - Dec. 1, 2012 in Leiden
- Future Directions

- **Cervix Cancer**

- Current studies and Future Directions — All

Update-PRO-Consort

- M Friedlander

Patient Reported Outcomes in Gynaecologic Cancer Clinical Trials

" Getting it right "

CONSORT-PRO recommendations

Reporting of Patient-Reported Outcomes in Randomized Trials

The CONSORT PRO Extension

JAMA, February 27, 2013—Vol 309, No. 8 815

1. PRO's be identified as a primary or secondary outcome in the abstract
2. A description of the of the hypothesis of the PROs and relevant domains be provided
3. That evidence of the PRO instrument's validity and reliability be provided or cited
4. That the statistical approaches for dealing with missing data be explicitly stated
5. That the PRO- specific limitations of the study findings and generalizability of the results to clinical practice be discussed

Checklist for phase 3 clinical trials

- Have you measured aspects of patients lives that patients consider important
- What is the hypothesis
- Will a PRO measure contribute to the study conclusions
- Have PRO endpoints been incorporated into protocol development
- Have you selected the right instrument- reliability/validity/responsiveness
- Is the study adequately powered for the QOL endpoint
- Do you have a SAP in place
- Mechanisms in place to reduce missing data
- Meets CONSORT-PRO extension guidelines

Ovary - Symptom Benefit Study

- M Friedlander

ANZGOG-0701
Symptom Benefit Study
Update and current status

Michael Friedlander on behalf of all
GCIG Symptom Benefit Study
Investigators

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PoCoG

ANZGOG
www.anzgog.org.au

Aims

- P**rimary aim** is to validate the MOST as a precise measure of symptom benefit for use in clinical trials in ROC where the aim of treatment is palliation/symptom benefit.
- **Secondary aims** include to:

- Determine the **minimum important difference** (MID) for clinically significant subjective improvement

-Compare patient reported with clinician reported toxicity;

- Develop a prognostic model to improve patient stratification in clinical trials.

Schema – Stage 2

Target Population

- Informed consent
- ≥ 18yrs
- Primary & Secondary Platinum Resistant/Refractory
- 3rd line or subsequent lines of treatment – incl Platinum Sensitive
- ECOG 0-3
- Life expectancy > 3 months
- Able to commence treatment within 2 weeks of registration
- Able to complete questionnaires independently

→ REGISTER →

Data Collection

- Baseline/Registration
- Each visit (3-4 wkly) until DP
- Every 3 – 4 wks if discontinue chemotherapy without DP
- Every 3 months following DP

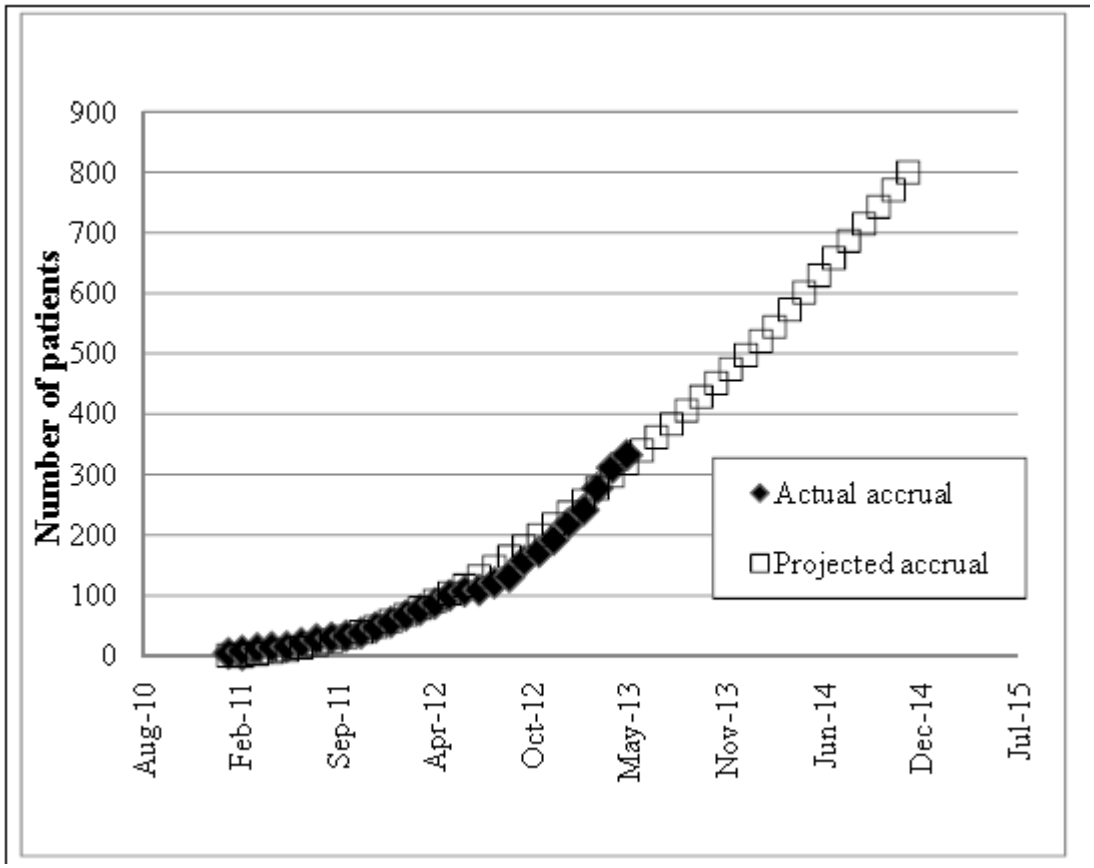
N=800

Recruitment – 27 May 2013

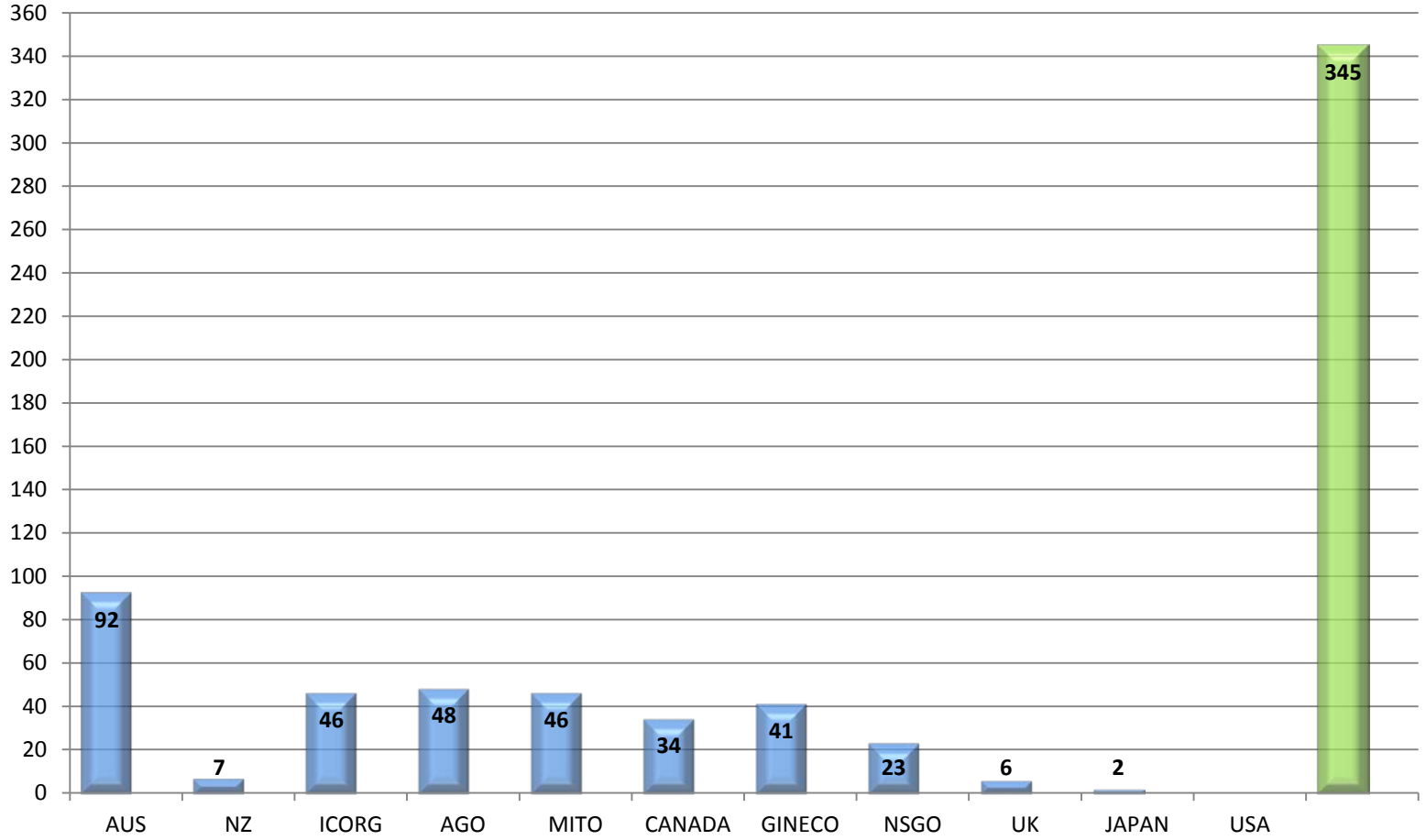
All countries/collaborative groups are now open to recruitment

ANZGOG	**Australia/New Zealand**
	Canada
ICORG	**Ireland**
MITO	**Italy**
NSGO	**Sweden - Denmark to open**
AGO	**Germany**
GINECO	**France**
	England
JGOG/GOTIC	**Japan**
	USA (Stanford) *(Opened 23 May 2013)*

Accrual


Number of patients
900
800
700
600
500
400
300
200
100
0
Aug-10
Feb-11
Sep-11
Apr-12
Oct-12
May-13
Nov-13
Jun-14
Dec-14
Jul-15
Actual accrual
Projected accrual

ANZGOG-0701 - Total Accrual



Ovary - Elderly

- EWOC (G Greyer)
- GOG 273 (for J Fleming)

ASCO 2013 – GCIG MEETING

Elderly Woman Ovarian Cancer trial (EWOC)

G. Freyer, MD, PhD

Lyon University Hospital

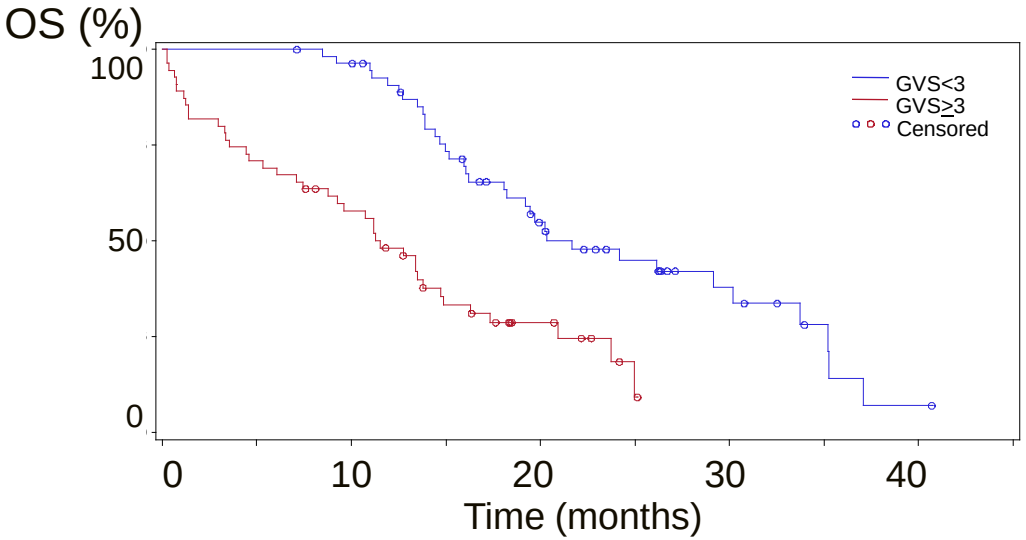
GINECO, Paris, France

Development of a Geriatric Vulnerability Score (GVS) in multivariate analysis

GVS = $\sum$ **vulnerability factors :**

- ADL score < 6
- IADL score < 25
- Albuminemia < 35g/L
- Lymphopenia < 1G/L
- HADS score > 14

=> Vulnerable if **GVS ≥ 3**



Freyer G et al. ASCO 2012, Abst. 9079

GOG 273 Update

Chemotherapy Toxicity in Elderly Women with Ovarian , Primary Peritoneal or Fallopian Tube Cancer

Gini Fleming

Chair GOG Working Group on Elderly

StudyChair

Vivian E. von Gruenigen, MD

GOG 273

- Open Aug 15, 2011
- Recently amended to make growth factor use optional in combination cohort
- Current Accrual (on May 17, 3013) at 177/185
- Maximum # for pts aged 70-74 has been met (25% of sample size)
- Analysis of carboplatin levels has started
- Proposed amendment for third arm has been submitted to DCP

Ovary – Expression III/IV

- J Sehouli

EUROP. KOMP'TZ-ZENTRUM EIERSTOCK-KREBS

TUMORZENTRUM CHARITÉ COMPREHENSIVE CANCER CENTER

NOGGO e.V.
Nord-Ostdeutsche Gesellschaft für Gynäkologische Onkologie e.V.

Expression III **ASCO 2012**

What do 676 primary and recurrent ovarian cancer (OC) patients expect from their doctors and therapy management? Results of a german survey of the North-Eastern German Society of Gynecological Oncology

G. Oskay-Özcelik, R. Chekerov, S. Neubert, K. Münstedt. H-J. Hindenburg, C. Liebrich, L.C. Hanker, R. Lorenz, P. Wimberger, J. Sehouli

www.expression3.de

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ESGO European Society of Gynaecological Oncology

ENGOT European Network of Gynaecological Oncology Trials groups

Belgium
FGOG Flanders

United Kingdom
SCOTROC

Austria
AGO

Germany
NOGGO

France
ARCAGY/GINECO

Spain
Geico

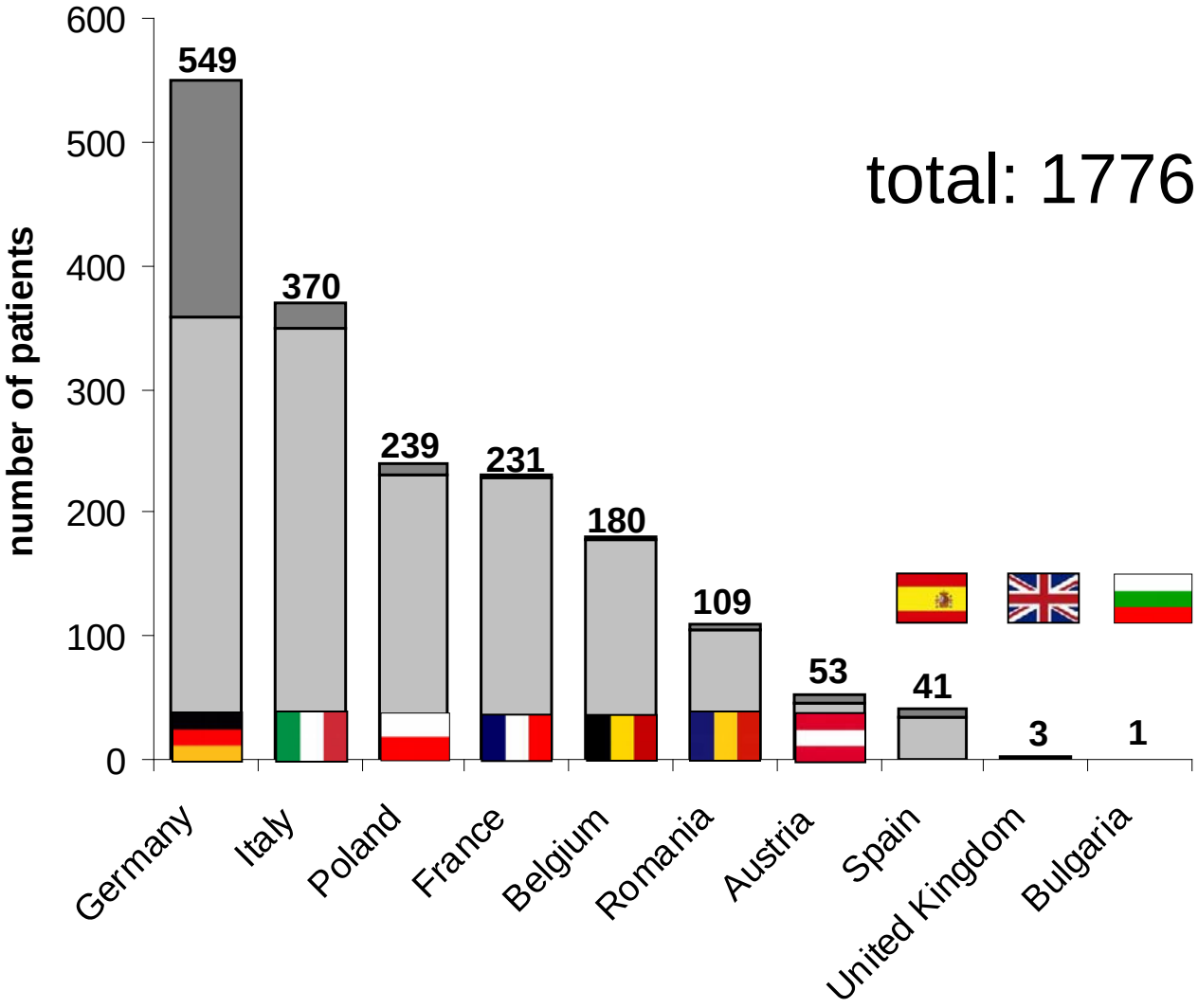
Romania

Bulgaria

Italy
MITO

Poland

EXPRESSION III



total: 1776 patients

ASCO 2013 General Poster Session, Abstract No 5569

Oskay-Oezcelik G, Keller M, Pignata S, Lorusso D, Joly F, Berton-Rigaud D, Vergote I, De Roover J, Maciejewski M, Jedryka M, Casado A, Mendiola C, Gonzalez A, Achimas P, Reimer D, Zeimet A, Hindenburg H-J., Richter R, Sehouli J.

What do primary and recurrent ovarian cancer patients expect from their doctors and therapy management? Results of a survey in eight European countries with 1,743 patients

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EXPRESSION IV- **Ovarian** Maintenance

What do primary and recurrent ovarian cancer (OC) patients expect from maintenance therapy?

ESGO European Society of Gynaecological Oncology
ENGOT European Network of Gynaecological Oncology Trials groups
GYNECOLOGIC CANCER INTERGROUP
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Objective

current available drugs for maintenance therapy have:

- different side effects
- administration forms
- schedules

→ identification of information needs and preferences regarding maintenance therapy among patients with ovarian cancer

Survey design

1. pilot study at max 2 German centres
   - questionnaire will be tested for comprehensibility and feasibility
   - max 100 patients
   - hard copy version

2. European survey (10-12 countries)
   - 200-300 patients / country
   - Internet version and hard copy version

Endometrium

- Update of Leiden (December 2012) brainstorming session (F Joly, J McAlpine)

Symptom Benefit Working Group: Endometrial cancer brainstorming session

GOAL 1 → Consideration of QOL components in endometrial cancer trials

GOAL 2 → What are the unmet needs/deficiencies in QOL studies in EM cancer today and how can we address these?

GOAL 3→ State of the art" endometrial cancer paper?
(2 papers on behalf of the GCIG)
- Review of QOL studies
- Didactic: tools, purpose/statements

Symptom Benefit Working Group: Endometrial cancer brainstorming session

NEXT: Intermediate-Long term (propositions)

- **Assessment of symptoms and pattern of care in women with recurrent endometrial cancer**
- Elderly trial? Including geriatric and SB assessment (pragmatic study?)
- Identifying survivorship issues for high risk endometrial cancers
- Intervention trials (symptoms post treatment)

➔Discussion: first : identify Practices and Patients symptoms

➔Survey for physicians

➔Patient questionnaire?